

EXHIBIT “A”

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO ALL CASES	PRETRIAL ORDER NO. (Non-Revision TVT Products Cases)

**ORDER REGARDING DISPOSITION OF NON-REVISION
GYNECARE TVT PRODUCTS CASES**

The motion (docket number____) of Defendants Ethicon, Inc., and Johnson & Johnson (collectively, "Ethicon")¹ for entry of an order establishing procedures for the voluntary dismissal or disposition of those cases of Plaintiffs who are alleging implantation of Ethicon's currently marketed Gynecare TVT products: Gynecare TVT Retropubic (TVT) or Abdominal (TVT-A) System, Gynecare TVT Obturator System (TVT-Obturator), Gynecare TVT Abbrevio Continence System (TVT-Abbrevio), and/or Gynecare TVT Exact Continence System (TVT-Exact), (hereinafter collectively "the Ethicon Gynecare TVT Products"), and who has not undergone any Revision Surgery as defined hereinafter, came on for hearing. The Court, having carefully considered this motion, the arguments and authorities presented by counsel, and the entire record, finds as follows:

I. INTRODUCTION

A. This MDL proceeding involves cases related to the implant of the Ethicon Gynecare TVT Products [Gynecare TVT Retropubic (TVT) or Abdominal (TVT-A) System, Gynecare TVT

¹ As used herein, "Ethicon" refers collectively to Johnson & Johnson, Ethicon LLC, Ethicon, Inc. as well as any of its former or present agents, employees, parent companies, subsidiaries, affiliated companies, directors, officers, design surgeons, employees, distributors, and detail representatives named in any action pending in MDL No. 2327

Obturator System (TVT-Obturator), Gynecare TVT Abbrevio Continence System (TVT-Abbrevio), and Gynecare TVT Exact Continence System (TVT-Exact)] as well as other Ethicon Pelvic Mesh Products used for the treatment of stress urinary incontinence or pelvic organ prolapse, including (1) four devices which are no longer marketed and/or sold by Ethicon: Prolift, Prolift+M, Prosima and TVT-Secur; and (2) two devices (Gynemesh PS and Prolene) which are marketed and sold by Ethicon separately.

B. Several thousand cases have been filed to date in this MDL proceeding in which plaintiffs have asserted claims relating to the implantation of Ethicon Gynecare TVT Products. This Order shall apply to all presently pending cases involving the Ethicon Gynecare TVT Product(s) and in which the plaintiff has not undergone a Revision Surgery and that have not otherwise been resolved between the parties. This court is well aware of the issues in this litigation and believes there is significant value to the plaintiffs who have not undergone a revision surgery in not being required to go forward with a case at this time when there is the possibility that they could be at risk of a surgery in the future and in preserving the right to proceed in the future in accordance with the terms of this Order if that occurs.

C. A federal district court has broad power to manage litigation, especially complex litigation, for the purpose of affording the parties a "just, speedy, and inexpensive" disposition of the action. See Fed. R. Civ. P. 1, 16, 26, 37, 42, 53 and 83; F. R. Ev. 706 (court-appointed experts); *see generally* Manual for Complex Litigation, Fourth §§ 10.1, 11, 20, 22, and 23. Among other things, the Court has the inherent authority and duty to identify, define, and resolve issues. *See, e.g.*, Fed. R. Civ. P. 16(c)(2) (authorizing "special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems").

D. The plan set forth below is intended to and should significantly reduce the burdens on this Court, allowing it to efficiently address, transfer, dismiss and/or try presently pending cases involving an Ethicon Gynecare TVT Product(s) when the Plaintiff has not undergone Revision Surgery. Judicial economy as well as the speedy, just, and fair resolution of such cases should be accomplished by the mechanisms set forth below, which are being established for the benefit of all parties.

IT IS THEREFORE ORDERED that the procedures for the dismissal or trial of such above described cases shall be, and hereby are, as follows:

Plaintiffs², who now have actions filed in or transferred to this MDL after process was duly and timely served as of the date of this Order, and who have had implanted one of Ethicon's Gynecare TVT Products in the United States or at a time when she was a lawful resident of the United States, and who have not undergone a Revision Surgery of the Gynecare TVT Product, are subject to this Order.

A "Revision Surgery" means surgery as defined in this paragraph which is for the revision or removal in whole or in part of an implanted Ethicon Gynecare TVT Product(s), or revision or removal of scar tissue, repair of fistula(s), or other surgeries (including surgical treatment for pain) related to or resulting from the implantation of an Ethicon Gynecare TVT Product(s), specifically related to the mesh. The term "Revision Surgery" will apply to surgeries utilizing either general, regional MAC, or local anesthesia

² Plaintiffs shall collectively include each of the individuals identified in Exhibit A hereto, who had one of these five Ethicon Gynecare TVT Product(s) (as defined in this Order) implanted, and their spouses, heirs, beneficiaries, agents, estates, executors, administrators, successors, assigns and other representatives that may be asserting a derivative claim against Ethicon on their behalf. The Plaintiffs identified on Exhibit A are "Non-Revised Plaintiffs" as defined in this Order.

undertaken for the purpose of dealing with medical problems related to the mesh. Such surgery must be performed by a duly licensed physician by and upon the recommendation of a physician.

A "Non-Revised Plaintiff" is a Plaintiff who has had an Ethicon Gynecare TVT Product(s) implanted and who has not undergone a Revision Surgery as described in the above paragraph. Each such Plaintiff is identified in Exhibit A, which is attached hereto and made a part hereof by reference, and shall hereinafter be referred to as a "Non-Revised Plaintiff" or collectively as "Non- Revised Plaintiffs." If Non-Revised Plaintiffs are mistakenly included or omitted on Exhibit A, then with agreement by the parties, Exhibit A will be amended from time to time in order to correct those mistakes.

Plaintiffs have argued that the claims of Non-Revised Plaintiffs should be preserved while their potential need for medical care continues. Ethicon's position is, in part, that such Non-Revised Plaintiffs do not currently have cognizable claims against it, as they have neither had a "Revision Surgery" and/or no licensed or competent physician, neither retained by plaintiff's counsel or a litigation funding company for purposes of performing such surgery has recommended any such "Revision Surgery."

These Non-Revised Plaintiffs desire that a procedure be established so that the Non-Revised Plaintiffs' claims against Ethicon may be voluntarily dismissed without prejudice, with the ability to refile in a federal district court of proper venue and jurisdiction within five (5) years of dismissal of the pending litigation should Plaintiff undergo a medically necessary Revision Surgery, be recommended for a medically necessary Revision Surgery, or otherwise undergo multiple qualifying procedures described below, within those five years. Under the unique circumstances of this litigation and to address in part this issue without prejudice to the positions

of any party, it appears to the Court that:

Ethicon, in consideration and in return for the voluntary dismissal of a Non-Revised Plaintiff's pending action without prejudice, within ninety (90) days of the election described in this Order, agrees that if a Non-Revised Plaintiff has Revision Surgery as defined herein within five (5) years of the date of dismissal of the pending action then the statute of limitations for her claim(s) shall commence on the date of that Revision Surgery or a recommendation for Revision Surgery, whichever first occurs. Ethicon agrees that the timely filing of a second lawsuit after a qualifying surgery shall not be barred by the statute of limitations or the statute of repose or any argument of equity regarding the timing of the initial lawsuit so long as the subsequent lawsuit is timely filed within the 5 year period based on the qualifying surgery.

For purposes of this order only, Ethicon agrees that plaintiffs who, although their treatment does not qualify as Revision Surgery within five years after the election, have more than one (1) in office revision of the mesh and who also have concomitant treatments of trigger point injections, vaginal physical therapy or utilization of vaginal Valium, that are demonstrated to be necessary by contemporaneous medical records and that are performed by a competent, licensed physician who is neither retained nor funded by a plaintiff's lawyer or a litigation funding entity for purposes of performing such procedures or treatments, nor where the litigation funding company has a relationship with the physician or the facility (or any related entity), will be treated the same as those plaintiffs who have a Revision Surgery within the five year period, as described above; however, the applicable statute of limitations shall begin to run upon the completion of the second of such multiple qualifying procedures.

In no event is Ethicon waiving or limiting its right to raise any applicable statute of limitations that may commence upon the date of any Revision Surgery, or the recommendation

for such surgery, whichever first occurs, or upon the completion of the second of such multiple qualifying procedures.

Accordingly, the Court orders the following election and trial preparation procedures to effectively manage its docket:

1. **Election Obligation** - Each Non-Revised Plaintiff identified on Exhibit "A", together with any of her derivative plaintiffs with an existing MDL lawsuit, shall file an election form (Exhibit B to this Order) in each individual case no later than ninety (90) days following the entry of this Order evidencing the Non-Revised Plaintiff's intent to either (i) dismiss her presently pending case without prejudice subject to the waiver provisions set forth hereinafter, or (ii) continue with her presently pending case without any waiver.

2. Each such Non-Revised Plaintiff, together, with any related derivative plaintiff with an existing MDL lawsuit, shall satisfy the election required in Paragraph 1 by filing with the Court a complete election form in her case and by simultaneously serving the election form and, if applicable, an Order of Dismissal Without Prejudice via electronic mail on Ethicon's attorney, Donna Brown Jacobs, at Butler Snow LLP using the following email address: dl2327election@butlersnow.com. This election form shall be filed in each individual case with the Court and served on Butler Snow within ninety (90) days following the entry of this Order.

3. Within thirty (30) days following the close of the election period, the parties shall jointly prepare and submit to the Court a list identifying: (a) the Non-Revised Plaintiffs who have elected not to dismiss their cases without prejudice in accordance with the provisions of this Order, together with the name of the plaintiff's lawyer who submitted the election form; (b) the Non-Revised Plaintiffs who have elected to dismiss their cases without prejudice in accordance with the provisions of this Order, together with the name of the plaintiff's lawyer

who submitted the election form; and (c) the Non-Revised Plaintiffs who have failed to file an election in accordance with this Order, together with the name of the plaintiff's lawyer who submitted the Plaintiff Profile Form, if submitted, for the plaintiff. If a Plaintiff fails to timely file an election pursuant to this Order, Ethicon may request in writing that the Court dismiss that Plaintiff's action without prejudice and after the opportunity for the plaintiff to be heard by the court.

4. **Election - Dismissal without Prejudice** - For any Non-Revised Plaintiff who elects to dismiss her case without prejudice and who has a Revision Surgery or the multiple qualifying procedures described above within five (5) years of the date of dismissal, Ethicon agrees that the statute of limitations on her claim shall commence on the date of her Revision Surgery, or the recommendation for such surgery, whichever first occurs, or upon the completion of the second of such multiple qualifying procedures.

5. **Reservation of claims against other defendants** - For those Non-Revised Plaintiffs that elect to dismiss their claims without prejudice pursuant to the terms of this Order, the dismissal shall be made as to Ethicon only. All remaining claims of such Non-Revised Plaintiff against any other defendants in MDLs No. 2187, 2325, 2326, 2387, 2440 or 2511 in the Southern District of West Virginia will remain viable and will continue to be prosecuted. This Order shall have no impact on the applicable statute of limitations, repose or otherwise against any other defendants in the case.

6. **Non-Revised Plaintiffs Who Do Not Elect To Dismiss**- In the event a Non-Revised Plaintiff elects not to dismiss her claim, but to continue her case, if the Non-Revised Plaintiff has not otherwise completed discovery pursuant to a previous Wave Order, then discovery shall be completed in each such case, as follows:

A. Each Non-Revised Plaintiff must establish that she has experienced a potentially compensable injury. To establish such injury, each Non-Revised Plaintiff shall serve upon Ethicon within forty-five (45) days after the election, if not done previously, the following: (1) a fully completed Plaintiff Profile Form ("PPF") with all required records authorizations; (2) complete implant records, including the operative report and any records establishing product identification; (3) the earliest medical record in which the alleged injury and/or symptom complaint is recorded, and all medical records relating to the plaintiff's claim. At the time of filing, plaintiff's counsel shall certify that the production is complete. The burden of proof, by a preponderance of the evidence, shall at all times rest on Plaintiff.

B. Each Non-Revised Plaintiff shall also produce to Ethicon the following documents within ninety (90) days following the election: (1) a fully completed Plaintiff Fact Sheet ("PFS") in the form and with the content specified by PTO 17; (2) documentation of any lost wages claimed in the PPF or PFS; (3) documentation of any medical expenses claimed and by whom; (4) any and all medical records of any type whatsoever (including photographs or videos) relating to any aspect of her gynecological history for the five (5) year period before the date of implantation of an Ethicon Gynecare TVT Product(s), including but not limited to, any pregnancies, hysterectomies, treatment for stress urinary incontinence or pelvic organ prolapse, and treatment for subsequent complaints (this time limitation shall not preclude a reasonable request for earlier or additional relevant medical records); (5) any and all

medical records of any type whatsoever relating to any alleged injury or complication for which she seeks compensation from Ethicon; (6) any and all medical records of any type whatsoever related in any way to the implantation, surgical revision, explanation or medical treatment of a medical device for treatment of pelvic floor prolapse or stress urinary incontinence; (7) a list of the known information (obtained after due diligence) pertaining to any potential medical or insurance liens, bankruptcy liens or claims by a bankruptcy trustee or debtor-in-possession, and any supporting documentation regarding each lien or claim; (8) a statement as to the fact of resolution, if any, of any claim against any other manufacturer or individual arising out of the implantation or use of a device to treat either stress urinary incontinence or pelvic organ prolapse; and (9) the documents produced must include product identification, the implant surgery records, any records of injuries claimed, and in-office revisit records, and all records of gynecological or Revision Surgeries involving other products and any other related procedures. Within thirty (30) days of the above procedure Boston Scientific will provide a defendants fact sheet in accordance with PTO 41.

C. If a Plaintiff on Exhibit A is subject to any wave discovery order, then all deadlines in such orders are no longer applicable as to that Plaintiff. Instead, within ninety (90) days after the close of the election period set forth herein, Plaintiff shall serve Rule 26 expert witness reports. Discovery as to the Plaintiff shall be conducted and completed within ninety (90) days after service of a Rule 26 expert witness report, and shall include but not be limited to discovery of any and all medical records; an independent medical examination; and depositions of the Plaintiff, her

current spouse or partner, prior spouses or partners, implanting surgeons, gynecological surgeons or other surgeons revising other products, gynecologists, primary-care doctors, and medical providers, and expert witnesses. Ethicon shall identify and produce expert witness reports within thirty (30) days after the plaintiff's expert reports are served. Expert disclosures for rebuttal purposes are due within twenty-one (21) days after service of Ethicon's expert witness reports. Expert witnesses who have previously been deposed on general subject matters shall not be deposed again without a showing of good cause except for the limited purpose of updating previous depositions on general subject matters or to question the witness about case specific opinions. In the absence of good cause shown, depositions shall be limited to three (3) hours in length, and the parties shall have equal time with respect to case specific treating physicians, unless one party fails to use its' entire allotted time; it is the intent of this order that neither party shall have more than 90 minutes of deposition time in the absence of agreement of the parties.

D. Absent a showing of good cause, no further discovery shall be taken from Ethicon or Johnson & Johnson regarding the company or regarding Ethicon's products. Ethicon may defend against all aspects of liability and damages on any and all grounds available to it. Dispositive motions, if any, by all parties shall be filed within thirty (30) days after the close of discovery.

E. Upon completion of discovery and to the extent her claim survives a dispositive motion, the case shall, as appropriate, either be placed on the trial calendar or remanded for trial before a federal district court of proper venue and

jurisdiction. Nothing herein operates to waive or diminish Ethicon's rights under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

F. Timely compliance with the deadlines in this Order is necessary for the prompt and fair resolution of any claims. Any failure to comply with the deadlines set forth by this Order is grounds for sanctions. In the event any party believes another party has not adequately provided the information required in this Order, then the party shall with specificity notify the other party of the missing material or deficiencies and the party shall have thirty (30) days to cure the deficiency. The parties may also file dispositive motions based on the materials provided at any time, and may supplement any motion with additional expert or fact affidavits or deposition testimony.

II. INTENT

The intent of this Order is to allow a Non-Revised Plaintiff's potential need for medical treatment to progress without the necessity of continuing this litigation and to allow such a Plaintiff to avoid incurring further expenses, unless and until she later undergoes a Revision Surgery, has such surgery recommended by a competent, qualified physician, or has the multiple qualifying procedures within five (5) years and elects to re-bring an action against Ethicon.

3. Nothing contained in this Order shall affect the obligations of Non-Revised Plaintiffs who file Complaints in this MDL after the entry of this Order to comply with all Orders previously or subsequently entered by the Court, including completion and service of a Plaintiff Profile Form (PPF), pursuant to PTO 17.

SO ORDERED AND DIRECTED, this the _____ day of _____ 2018.

HONORABLE JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE